

EXHIBIT B

In the Matter of:

FTC, et al. v. Quincy Bioscience Holding, et al.

October 5, 2021

Lee-Jen Wei, Ph.D. - Confidential

Condensed Transcript with Word Index



For The Record, Inc.
(301) 870-8025 - www.ftrinc.net - (800) 921-5555

1	1	3
1	UNITED STATES DISTRICT COURT	1
2	SOUTHERN DISTRICT OF NEW YORK	2
3		3
4	FEDERAL TRADE COMMISSION and)	4
5	THE PEOPLE OF THE STATE OF)	5
6	NEW YORK, BY LETITIA JAMES,)	6
7	ATTORNEY GENERAL OF THE STATE)	7
8	OF NEW YORK,)	8
9	Plaintiffs,)	9
10	-vs-) Case No.	10
11	QUINCY BIOSCIENCE HOLDING) 1:17-CV-00124-LLS	11
12	COMPANY, INC., a corporation,)	12
13	et al.,)	13
14	Defendants.)	14
15	-----)	15
16		16
17	CONFIDENTIAL - ATTORNEYS' EYES ONLY	17
18		18
19	The videotape deposition of LEE-JEN	19
20	WEI, PH.D., was taken on Tuesday, October 5,	20
21	2021, commencing at 9:33 a.m., remotely, before	21
22	Tammy S. Newton, Notary Public.	22
23		23
24		24
25		25
2	2	4
1	A P P E A R A N C E S	1
2	ON BEHALF OF PLAINTIFFS:	2
3	ANNETTE SOBERATS, ESQUIRE	3
4	EDWARD GLENNON, ESQUIRE	4
5	ANDREW WONE, ESQUIRE	5
6	Federal Trade Commission	6
7	600 Pennsylvania Avenue, N.W.	7
8	Washington, D.C. 20850	8
9	asoberats@ftc.gov	9
10	and	10
11	KATE MATUSCHAK, ESQUIRE	11
12	Attorney General of the State of	12
13	New York	13
14	Assistant Attorney General	14
15	Consumer Frauds and Protection Bureau	15
16	28 Liberty Street	16
17	New York, New York 10005	17
18	(212) 416-6189	18
19	kate.matuschak@ag.ny.gov	19
20		20
21		21
22		22
23		23
24		24
25		25
1	C O N T E N T S	1
2	EXAMINATION OF LEE-JEN WEI, PH.D.	2
3	By Ms. Soberats	3
4	By Ms. Matuschak	4
5		5
6	DEPOSITION EXHIBITS	6
7	LJ-1 - Rebuttal Expert Report of	7
8	Professor Lee-Jen Wei	8
9	LJ-2 - Complaint for Permanent Injunction	9
10	and Other Equitable Relief	10
11	LJ-3 - Madison Memory Study	11
12	LJ-4 - Lerner MMS Write-up	12
13	LJ-5 - E-mail	13
14	LJ-6 - AD8 2-3 Subgroup Analysis	14
15	LJ-7 - Cogstate Data Guidelines for	15
16	Analysis	16
17	LJ-8 - JAMA Open Article	17
18	LJ-9 - Viewpoint Article	18
19	LJ-10 - MMS Write-up Interim Data	19
20		20
21		21
22		22
23		23
24		24
25		25

45

1 **language in this paragraph containing the**
 2 **complaint allegations referring to relatively**
 3 **healthy, non-demented adults?**

4 MR. GRAHAM: Objection.

5 THE WITNESS: Well, ma'am, I'm not
 6 expert in neuroscience. I cannot quantify this
 7 paragraph it's related to healthy adults or not.
 8 I'm basically a statistician. I'm not in a
 9 position to say to you by reading this paragraph
 10 using applicable to the healthy subject or not.

11 BY MS. SOBERATS:

12 **Q Please turn to the next page, page 27,**
 13 **and I'd like you to scroll to Count II of the**
 14 **complaint.**

15 A Yes, ma'am.

16 **Q This count contains the false proof**
 17 **claims that the Federal Trade Commission is**
 18 **challenging.**

19 MR. GRAHAM: Objection.

20 BY MS. SOBERATS:

21 **Q And here the Federal Trade Commission**
 22 **alleges that defendants claimed "Prevagen is**
 23 **clinically shown to improve memory. Prevagen is**
 24 **clinically shown to improve memory in 90 days.**
 25 **Prevagen is clinically shown to reduce memory**

46

1 **problems associated with aging. And Prevagen is**
 2 **clinically shown to provide other cognitive**
 3 **benefits, including but not limited to healthy**
 4 **brain function, a sharper mind, and clearer**
 5 **thinking."**

6 **Do you see those claims in Count II of**
 7 **this complaint?**

8 MR. GRAHAM: Objection.

9 THE WITNESS: Well, ma'am, with all
 10 due respect, I see that you put me in a very
 11 difficult position. I'm not a neuroscientist. I
 12 cannot convert what you're saying ABCD into the
 13 clinical meaning for Wei.

14 Because if you think about it, you're
 15 saying Prevagen is clinically shown. I cannot
 16 say that. I'm not clinical person. Please also,
 17 everywhere you use the word "clinically shown,"
 18 "clinically shown," how can I tell you it's
 19 clinically shown. I can tell you from a
 20 statistical point of view, statistically shown or
 21 not.

22 I'm really sorry. This is not my
 23 actual -- the expertise. I can tell you Prevagen
 24 is a clinically meaningful dietary supplement to
 25 any of the functional CNS function. Basically I

47

1 can't.

2 BY MS. SOBERATS:

3 **Q Understood. Were you aware that the**
 4 **Federal Trade Commission was challenging claims**
 5 **that Prevagen is clinically shown to provide**
 6 **these benefits?**

7 MR. GRAHAM: Objection.

8 THE WITNESS: Well, ma'am, you show me
 9 this document. You said this is FTC filed a
 10 complaint against the sponsor. I said, Well
 11 that's correct. You show me this document
 12 including those claims, probably false proof
 13 claims. I'm not in a position to say Prevagen is
 14 or not clinically shown.

15 I don't even know when you're talking
 16 about clinically, how do you define this word
 17 "clinically"? Are you telling me from all those
 18 nine tests what kind of improvement from the
 19 treatment will be classified as a clinically
 20 meaningful benefit? You know, you tell me. Then
 21 I would be happy to entertain your question.

22 I bet you, you ask 10 different
 23 clinical people, they would give you 10 different
 24 opinions. What are you talking about? Right.
 25 This is such a gray area.

48

1 I think, ma'am, with all due respect,
 2 you should get the clinical expertise to confirm
 3 what you are asking me at this moment.

4 BY MS. SOBERATS:

5 **Q Had you seen these claims before**
 6 **today, Dr. Wei?**

7 A Ma'am, I -- I am sorry. I don't
 8 remember I read this complaint.

9 **Q Dr. Wei, in your report, you included**
 10 **a citation to the Prevagen.com website. Did you**
 11 **review that website?**

12 A I believe I read that website even
 13 before the -- I put a -- the report together.
 14 Since then, I didn't go back to the website to
 15 refresh my memory. So I don't recall what
 16 exactly it is saying now.

17 Basically, ma'am, my report are based
 18 on the material I provide in Appendix B, and I --
 19 my assignments, as you know very well,
 20 two-folded. One is to assess what Dr. Wittes and
 21 Dr. Sano's report, if they actually -- their
 22 claims are correct or not. That's the first
 23 assignment I had.

24 The second assignment, based on all
 25 the reports I received from Quincy Bioscience,

185

1 You're using totality of nine outcomes
2 as the primary endpoint, instead of you pick up a
3 separate -- one is a primary and the rest eight
4 guys are secondary. They don't do that. Right.
5 They wanted to look at the data totality, but
6 unfortunately, when they analyze data, they
7 didn't do that using totality of evidence.

8 **Q They analyzed each task separately?**

9 A Yeah. That was a mistake. Actually,
10 but -- those guys are not -- they were not expert
11 in statistics back in 2011. And I don't think
12 they understand it how to combine information.
13 Nowadays we know. We know how to do that.

14 **Q So how would you combine the nine
15 tasks into one primary endpoint? Would you
16 calculate a composite score?**

17 A Yeah. That's a very good question.
18 You -- one approach is just like saying for each
19 patient, I get a composite score, whichever they
20 want to call it. From a clinical utility point
21 of view, I have a nine tests. Each test has a
22 score. You add it up and say, This is beautiful.
23 You are doing very well. Right.

24 Another way is more like a statistical
25 argument. You're saying I have a nine tests. I

186

1 still following your convention wisdom. For each
2 outcome, I get a summary, right, for the
3 difference between the two groups. Then I say, I
4 have a nine summary numbers in front of me.

5 Then I ask myself, Hey, listen, look
6 at this nine outcomes, how they actually
7 correlate with each other. If those nine
8 outcomes, they all tended to go to your direction
9 in favor of your treatment. I said, Wow, this is
10 beautiful. You know, if there is no difference,
11 my -- my outcomes should be fluctuated around
12 zero, right, back and forth, back and forth.
13 It's random.

14 Now you say the majority of outcome
15 result, they only in favor of yours. You think
16 there's a very strong signal. The answer is yes
17 actually. In fact, we can quantify this idea by
18 the paper cited below, and it's one of my
19 students Daniel Li where he publish in I think --
20 I see it two years ago in JAMA, JAMA Open.

21 COURT REPORTER: What was that?

22 THE WITNESS: In JAMA. J-A-M-A,
23 O-P-E-N.

24 BY MS. SOBERATS:

25 **Q And the paper you're referring to, is**

187

1 **it in your materials reviewed list?**

2 A That was my paper.

3 **Q You're referring to the Li Daniel
4 paper from JAMA?**

5 A Yes, ma'am.

6 **Q Okay. Did you calculate a composite
7 score for the nine Cogstate tasks in the Madison
8 Memory Study?**

9 A I need clinical folks help me
10 construct a composite score across nine.
11 Statistician cannot construct so-called score --
12 composite score, as you know very well, ma'am.

13 **Q Did you attempt to conduct the other
14 analysis that you just described about looking at
15 how the nine outcomes, I think you said,
16 correlate together?**

17 MR. GRAHAM: Objection.

18 THE WITNESS: They actually go
19 together, right. For example, if you have nine
20 outcomes, like seven outcomes, they are all in
21 favor of yours. Now you ask yourself and say,
22 can you quantify the chance. And if there is no
23 difference between the two arms, what will be the
24 chance of observing this pretty interesting
25 positive trend. That's the method Daniel Li

188

1 presented.

2 Actually, it was older method where he
3 published back in 1984. The method was called
4 Wei and Lachin, which was a very popular clinical
5 trial. You know, but unfortunately, I don't have
6 the data from Bio -- Quincy Bioscience, and that
7 was not my assignment either. So I didn't -- I
8 didn't analyze it using this very nice way to do
9 it.

10 BY MS. SOBERATS:

11 **Q Dr. Wei, I just revealed a new
12 exhibit. It should load on the left side of your
13 screen for Agile Law. I'm showing you what I
14 marked as exhibit LJ-4.**

15 **(Deposition Exhibit Number LJ-4 was
16 marked for identification and attached to the
17 transcript.)**

18 THE WITNESS: Yes, ma'am.

19 BY MS. SOBERATS:

20 **Q At various points throughout the day
21 you've referred to a document with the title
22 "Clinical Trial Synopsis" from 2016. Is this the
23 document you were referring to?**

24 A Yes, ma'am.

25 **Q Okay. So this is a write-up titled**

297

1 Right. And the corresponding treatment arm, Day
 2 90 is 27.25. Okay. It's like the previous
 3 counsel took a difference between 27.25 minus
 4 25.19. That's a single number and you put aside.
 5 And then you start to figure out what's the
 6 standard error. Right.
 7 So the standard error is very simple.
 8 So you have standard deviation for placebo arm
 9 5.163. Right. Okay. That's a standard
 10 deviation. You take a square of this value, so
 11 roughly 25. 25 divided by 40, which is sample
 12 size for this group, and then you plus the
 13 similar quantity using the treated arm standard
 14 deviation 5.102. You also square this guy. By
 15 this time, you divide it by 60. Right.
 16 So that's -- you add it up, that's two
 17 variances. Take a square root of this two guys
 18 to sum it up, multiply by two. So you plus this
 19 quantity, this upper bound, minus this quantity,
 20 that's lower bound. That's it. That's 95
 21 percent confidence interval.
 22 Unfortunately, you know, neither Dr.
 23 Wittes or Dr. Sano noticed this part. Right.
 24 They didn't even calculate the confidence
 25 interval, just like me. They actually

298

1 concentrate on p-values.
 2 MS. MATUSCHAK: Thank you, Dr. Wei. I
 3 have no further questions.
 4 THE WITNESS: Okay.
 5 MS. MATUSCHAK: Do the defendants have
 6 any questions?
 7 MR. de LEEUW: I have nothing.
 8 THE WITNESS: Sorry. Glenn, I cannot
 9 hear you.
 10 MR. GRAHAM: Nothing from our end,
 11 L.J.
 12 MR. de LEEUW: Nothing here either.
 13 Thanks.
 14 VIDEOTAPE OPERATOR: Here ends today's
 15 deposition. Off the record at 5:50 p.m.
 16 (Whereupon, the deposition concluded at 5:50
 17 p.m.)
 18
 19
 20
 21
 22
 23
 24
 25

299

1 * * *
 2 ACKNOWLEDGMENT OF DEPONENT
 3
 4 I, Lee-Jen Wei, do hereby acknowledge I have read
 5 and examined the foregoing pages of testimony,
 6 and the same is a true, correct and complete
 7 transcription of the testimony given by me, and
 8 any changes and/or corrections, if any, appear in
 9 the attached errata sheet signed by me.

13 _____
 14 Date Lee-Jen Wei
 15
 16
 17
 18
 19
 20
 21
 22
 23
 24
 25

300

1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC
 2 I, Tammy S. Newton, the officer before
 3 whom the foregoing proceedings was taken, do
 4 hereby certify that the foregoing transcript is a
 5 true and correct record of the proceedings; that
 6 said proceedings were taken by me
 7 stenographically and thereafter reduced to
 8 typewriting under my supervision; and that I am
 9 neither counsel for, related to, nor employed by
 10 any of the parties to this case and have no
 11 interest, financial or otherwise, in its outcome.
 12 IN WITNESS WHEREOF, I have hereunto set
 13 my hand and affixed my notarial seal this 13th
 14 day of October, 2021.
 15 My commission expires:
 16 3/05/2022
 17
 18 s/Tammy S. Newton
 19 Notary Public in and for the
 20 State of Maryland
 21
 22
 23
 24
 25